Mr. John Lee
Schwarz Pharma USA, Inc.
1101 “C” Avenue West, Freeman Field
Seymour, Indiana 47274

Re: Minor Source Modification No:
071-11653-00023

Dear Mr. Lee:

Schwarz Pharma USA, Inc. applied for a Part 70 operating permit (T071-7162-00023) on November 14, 1996 for a plant that manufactures pharmaceutical products. An application to modify the source was received on December 13, 1999. Pursuant to 326 IAC 2-7-10.5 the following emission units are approved for construction at the source:

(a) Colyte production area, identified as emission unit- 01 (EU-01). This area will manufacture different types of Colyte, which involve a dry mix blending operation, product container filling and labeling. This production area is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse, EU-01;

(b) Phase IIIA production area, identified as emission unit–02 (EU-02). This area will manufacture several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 lbs/batch of raw material and the PM emissions are controlled by baghouse, EU-02; and

(c) Two (2) natural gas-fired boilers, identified as EU-03 and EU-04, each has a heat input capacity of 20.9 million British Thermal Units per hour (mmBtu/hr).

The proposed Minor Source Modification approval will be incorporated into the pending Part 70 permit application pursuant to 326 IAC 2-7-10.5(l)(3). The source may begin operation upon issuance of the source modification approval.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter call (800) 451-6027, press 0 and ask for Aida De Guzman or extension (3-4972), or dial (317) 233-4972.

Sincerely,

Paul Dubenetzky, Chief
Permits Branch
Office of Air Management

Attachments
APD
cc: File - Jackson County
U.S. EPA, Region V
Jackson County Health Department
Air Compliance Section Inspector - Joe Foyst
Compliance Data Section - Karen Nowak
Administrative and Development - Janet Mobley
Technical Support and Modeling - Michele Boner

PART 70 MINOR SOURCE MODIFICATION
OFFICE OF AIR MANAGEMENT

Schwarz Pharma USA, Inc.
1101 "C" Avenue West, Freeman Field
Seymour, Indiana 47274

(herein known as the Permittee) is hereby authorized to construct and operate subject to the conditions contained herein, the emission units described in Section A (Source Summary) of this approval.

This approval is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Source Modification No.: 071-11653-00023	
Issued by: Paul Dubenetzky, Branch Chief Office of Air Management	Issuance Date:

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SECTION A SOURCE SUMMARY

This approval is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Management (OAM). The information describing the emission units contained in conditions A.1 through A.2 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this approval pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

The Permittee owns and operates a pharmaceutical plant.

Responsible Official:	John Lee
Source Address:	1101 “C” Avenue West, Freeman Field, Seymour, Indiana 47274
Mailing Address:	1101 “C” Avenue West, Freeman Field, Seymour, Indiana 47274
Phone Number:	(812) 523-5405
SIC Code:	3931
County Location:	Jackson County
County Status:	Attainment for all criteria pollutants
Source Status:	Part 70 Permit Program Minor Source, under PSD Rules;

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]

Thissource is approved to construct and operate the following new emission units and pollution control devices:

(a) Colyte production area, identified as emission unit- 01 (EU-01). This area will manufacture different types of Colyte, which involve a dry mix blending operation, product container filling and labeling. This production area is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse, EU-01;

(b) Phase IIIA production area, identified as emission unit–02 (EU-02). This area will manufacture several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 lbs/batch of raw material and the PM emissions are controlled by baghouse, EU-02; and

(c) Two (2) natural gas-fired boilers, identified as EU-03 and EU-04, each has a heat input capacity of 20.9 million British Thermal Units per hour (mmBtu/hr).

A.3 Part 70 Permit Applicability [326 IAC 2-7-2]

This stationary source is required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because:

(a) It is a major source, as defined in 326 IAC 2-7-1(22);

(b) It is a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 - Applicability).

SECTION B GENERAL CONSTRUCTION CONDITIONS

B.1 Permit No Defense [IC 13]

This approval to construct does not relieve the Permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

B.2 Definitions [326 IAC 2-7-1]

Terms in this approval shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, any applicable definitions found in IC 13-11, 326 IAC 1-2 and 326 IAC 2-7 shall prevail.

B.3 Effective Date of the Permit [IC13-15-5-3]

Pursuant to IC 13-15-5-3, this approval becomes effective upon its issuance.

B.4 Revocation of Permits [326 IAC 2-1.1-9(5)][326 IAC 2-7-10.5(i)]

Pursuant to 326 IAC 2-1.1-9(5)(Revocation of Permits), the Commissioner may revoke this approval if construction is not commenced within eighteen (18) months after receipt of this approval or if construction is suspended for a continuous period of one (1) year or more.

SECTION C GENERAL OPERATION CONDITIONS

C.1 Certification [326 IAC 2-7-4(f)][326 IAC 2-7-6(1)][326 IAC 2-7-5(3)(C)]

(a) Where specifically designated by this approval or required by an applicable requirement, any application form, report, or compliance certification submitted under this approval shall contain certification by a responsible official of truth, accuracy, and completeness. This certification, shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

(b) One (1) certification shall be included, on the attached Certification Form, with each submittal.

(c) A responsible official is defined at 326 IAC 2-7-1(34).

C.2 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]

(a) The Permittee must comply with the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this approval.

(b) Any application requesting an amendment or modification of this approval shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Management
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

Any such application should be certified by the “responsible official” as defined by 326 IAC 2-7-1(34) only if a certification is required by the terms of the applicable rule

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

C.3 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following, unless otherwise stated in this approval:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

Record Keeping and Reporting Requirements

C.4 Monitoring Data Availability [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)]

(a) With the exception of performance tests conducted in accordance with Section C-Performance Testing, all observations, sampling, maintenance procedures, and record keeping, required as a condition of this approval shall be performed at all times the equipment is operating at normal representative conditions.

(b) As an alternative to the observations, sampling, maintenance procedures, and record keeping of subsection (a) above, when the equipment listed in Section D of this approval is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this approval.

(c) If the equipment is operating but abnormal conditions prevail, additional observations and sampling should be taken with a record made of the nature of the abnormality.

(d) If for reasons beyond its control, the operator fails to make required observations, sampling, maintenance procedures, or record keeping, reasons for this must be recorded.

(e) At its discretion, IDEM may excuse such failure providing adequate justification is documented and such failures do not exceed five percent (5%) of the operating time in any quarter.

(f) Temporary, unscheduled unavailability of staff qualified to perform the required observations, sampling, maintenance procedures, or record keeping shall be considered a valid reason for failure to perform the requirements stated in (a) above.

C.5 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]

(a) Records of all required monitoring data and support information shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be kept at the source location for a minimum of three (3) years and available upon the request of an IDEM, OAM, representative. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a written request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

(b) Records of required monitoring information shall include, where applicable:

(1) The date, place, and time of sampling or measurements;

(2) The dates analyses were performed;

(3) The company or entity performing the analyses;

(4) The analytic techniques or methods used;

(5) The results of such analyses; and

(6) The operating conditions existing at the time of sampling or measurement.

(c) Support information shall include, where applicable:

(1) Copies of all reports required by this approval;

(2) All original strip chart recordings for continuous monitoring instrumentation;

(3) All calibration and maintenance records;

(4) Records of preventive maintenance shall be sufficient to demonstrate that failure to implement the Preventive Maintenance Plan did not cause or contribute to a violation of any limitation on emissions or potential to emit. To be relied upon subsequent to any such violation, these records may include, but are not limited to: work orders, parts inventories, and operator's standard operating procedures. Records of response steps taken shall indicate whether the response steps were performed in accordance with the Compliance Response Plan required by Section C - Compliance Monitoring Plan - Failure to take Response Steps, of this approval, and whether a deviation from an approval condition was reported. All records shall briefly describe what maintenance and response steps were taken and indicate who performed the tasks.

(d) All record keeping requirements not already legally required shall be implemented within ninety (90) days of approval issuance.

C.6 General Reporting Requirements [326 IAC 2-7-5(3)(C)]

(a) The reports required by conditions in Section D of this approval shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

(b) Unless otherwise specified in this approval, any notice, report, or other submission required by this approval shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAM, on or before the date it is due.

(c) Unless otherwise specified in this approval, any semi-annual report shall be submitted within thirty (30) days of the end of the reporting period. The reports do not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(d) The first report shall cover the period commencing on the date of issuance of this approval and ending on the last day of the reporting period.

SECTION D.1 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]

Insignificant Activities:

(a) Colyte production area, identified as emission unit- 01 (EU-01). This area will manufacture different types of Colyte, which involve a dry mix blending operation, product container filling and labeling. This production area is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse, EU-01;

(b) Phase IIIA production area, identified as emission unit–02 (EU-02). This area will manufacture several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 lbs/batch of raw material and the PM emissions are controlled by baghouse, EU-02.

Emission Limitations and Standards

D.1.1 Particulate Matter (PM) [326 IAC 6-3]

Pursuant to 326 IAC 6-3 (Process Operations), the allowable PM emission rate from the following facilities shall be limited as follows:

Facility/Operation	Process Weight (ton/hr)	PM Emissions Limit (lbs/hr)
Colyte Production Line	0.01	0.187
Phase IIIA Production Line	0.0044	0.11

The pounds per hour limitation shall be calculated with the following equation:
Interpolation and extrapolation of the data for the process weight rate up to 60,000 pounds per hour shall be accomplished by use of the equation:

$E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

Compliance Determination Requirements

D.1.2 Testing Requirements [326 IAC 2-8-5(a)(1), (4)][326 IAC 2-1.1-11]

The Permittee is not required to test this facility by this permit. However, IDEM may require compliance testing when necessary to determine if the facility is in compliance. If testing is required by IDEM, compliance with the PM limit specified in Condition D.1.1 shall be determined by a performance test conducted in accordance with Section C - Performance Testing.

Record Keeping and Reporting Requirements

D.1.3 Record Keeping Requirements

(a) To document compliance with Conditions D.1.1 the Permittee shall maintain records of the process throughput weight monthly. Records shall include purchase orders, and invoices.

(b) These records shall be maintained in accordance with Section C - General Record Keeping Requirements.

SECTION D.2 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]

(c) Two (2) natural gas-fired boilers, identified as EU-03 and EU-04, each has a heat input capacity of 20.9 million British Thermal Units per hour (mmBtu/hr).

Emission Limitations and Standards

D.2.1 Particulate Matter (PM)

Pursuant to 326 IAC 6-2-4, the Particulate Matter (PM) emissions from the two (2) 20.9 million British Thermal Units (mmBtu) boilers shall be limited as follows:

Facility/Operation	PM Emissions Limit (lb/mmBtu)
Boiler, EU-03	0.40
Boiler, EU-04	0.40

This limitation is based on the following equation:

$Pt = 1.09/Q^{0.26}$

Where: Pt = Pounds of PM emitted per million Btu (lb/mmBtu) heat input.
Q = Total source maximum operating capacity rating in mmBtu/hr

D.2.2 New Source Performance Standards [326 IAC 12 and 40 CFR § 60.40c, Subpart Dc]

Pursuant to 326 IAC 12 and 40 CFR § 60.40c, Subpart Dc- Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units, the proposed two (2) 20.9 mmBtu/hr boilers EU-03 and EU-04 are subject to the § 60.48 Subsections (a), (g) and (i) of this NSPS.

(a) Pursuant to Subsection (a) of § 60.48, the owner/operator of the two (2) boilers shall submit notification of the date of construction, or reconstruction, anticipated startup and actual startup as provided by § 60.7 of this part. The notification shall include:

(1) The design heat input capacity of the two (2) boilers and identification of the fuel to be combusted; and

(2) The annual capacity factor at which the owner/operator anticipates operating the two (2) boilers, based on all fuels fired and based on individual fuel fired.

(b) Pursuant to Subsection (g) § 60.48, the owner/operator of the two (2) boilers shall maintain records of the amounts of fuel combusted during each month.

(c) Pursuant Subsection (i) § 60.48, all records required in this Section shall be maintained by the owner or operator of the two (2) boilers for a period of two (2) years following the date of such record.

Compliance Determination Requirement

D.2.3 Testing Requirements [326 IAC 2-8-5(a)(1), (4)][326 IAC 2-1.1-11]

The Permittee is not required to test this facility by this permit. However, IDEM may require compliance testing at any specific time when necessary to determine if the facility is in compliance. If testing is required by IDEM, compliance with the PM limit specified in Condition D.1.1 shall be determined by a performance test conducted in accordance with Section C - Performance Testing.

Record Keeping and Reporting Requirements [326 IAC 2-8-4(3)] [326 IAC 2-8-16]

D.2.4 Record Keeping Requirement

(a) To document compliance with Conditions D.2.1, and D.2.2 the Permittee shall maintain records of the amount of the natural gas combusted. Records maintained shall be complete and sufficient to establish compliance with the PM emission limits established in Condition D.2.1.

(b) These records shall be maintained in accordance with Section C - General Record Keeping Requirements.

Indiana Department of Environmental Management
Office of Air Management

Technical Support Document (TSD) for a Part 70 Minor Source Modification

Source Background and Description

Source Name:	Schwarz Pharma USA, Inc.
Source Location:	1101 "C" Avenue West, Freeman Field Seymour, Indiana 47274
County:	St. Joseph
SIC Code:	2834
Operation Permit No.:	T071-7162-00023
Operation Permit Issuance Date:	Pending
1st Minor Source Modification No.:	071-11653-00023
Permit Reviewer:	Aida De Guzman

The Office of Air Management (OAM) has reviewed a modification application from Schwarz Pharma USA, Inc. relating to the addition of new production areas to the existing pharmaceutical plant. The following are the proposed emission units and pollution control devices:

(a) Colyte production area, identified as emission unit- 01 (EU-01). This area will manufacture different types of Colyte, which involve a dry mix blending operation, product container filling and labeling. This production area is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse, EU-01;

(b) Phase IIIA production area, identified as emission unit–02 (EU-02). This area will manufacture several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 lbs/batch of raw material and the PM emissions are controlled by baghouse, EU-02; and

(c) Two (2) natural gas-fired boilers, identified as EU-03 and EU-04, each has a heat input capacity of 20.9 million British Thermal Units per hour (mmBtu/hr).

History

On January 7, 1998, Schwarz Pharma USA, Inc., submitted an application to the OAM requesting to add production areas to their existing plant. Schwarz Pharma USA, Inc. submitted a Part 70 permit application 071-7162-00023 on November 14, 1996.

Stack Summary

Stack ID	Operation	Height (feet)	Diameter (feet)	Flow Rate (acfm)	Temperature (^{0}F)
EU-01	Colyte Production Area	Rectangular		46,500	708
EU-02	Phase IIIA	Rectangular		46,500	708

Recommendation

The staff recommends to the Commissioner that the Part 70 Minor Source Modification be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on December 13, 1999. Additional information was received on January 5, 2000.

Emission Calculations

(a) Natural Gas Combustion Emissions: See Page 1 of 1 TSD Appendix A for detailed emission calculations on the two (2) proposed boilers.

(b) Colyte Production Area Emissions:

Colyte Production Process Information	
Maximum Process Weight:	3,956 pounds per batch
Full Cycle:	8 days/batch (3 days mixing & 5 days filling
Maximum no. of batches/year	66 batches/yr

Process Description	Throughput (lb/batch)	Emission factor (lb PM/ton of material)	PM=PM10 Uncontrolled Emissions (ton/year)	PM = PM10 Controlled Emissions (ton/year)
Raw Material Weigh-Up	3,956	5 lb/ton	0.33	3.3×10^{-5}
Raw Material Mixing	3,956	5 lb/ton	0.33	3.3×10^{-5}
TOTAL EMISSIONS			0.66	6.6×10^{-5}

Methodology:
PM Emissions = Throughput, lb/batch * batches/yr * ton/2000 lb * Ef, lb/ton * ton/2000 lb

(c) Phase IIIA Production Area Emissions:

Phase IIIA Production Process Information	
Maximum Process Weight:	1,690.3 pounds per batch
Full Cycle:	8 days/batch (3 days mixing & 5 days filling
Maximum no. of batches/year	66 batches/yr

Process Description	Throughput (lb/batch)	Emission factor (lb PM/ton of material)	PM=PM10 Uncontrolled Emissions (ton/year)	PM=PM10 Controlled Emissions (ton/year)
Raw Material Weigh-Up	1,690.3	5 lb/ton	0.14	1.4×10^{-5}
Raw Material Mixing & Filling of Tablets & Capsules	1,690.3	5 lb/ton	0.14	1.4×10^{-5}
TOTAL EMISSIONS			0.28	2.8×10^{-5}

Methodology:
PM Emissions = Throughput, lb/batch * batches/yr * ton/2000 lb * Ef, lb/ton * ton/2000 lb

Potential To Emit of Modification

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as "the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA."

This table reflects the PTE before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	1.34
PM-10	2.34
SO_2	0.2
VOC	1.0
CO	15.4
NO_x	18.4

Justification for Modification

The Part 70 Operating permit is being modified through a Part 70 Minor Source Modification. This modification is being performed pursuant to 326 IAC 326 IAC 2-7-10.5(d)(4), because the Oxides of Nitrogen (NOx) is emitted at a rate greater than 10 tons per year but less than 25 tons per year.

County Attainment Status

The source is located in Jackson County.

Pollutant	Status (attainment, maintenance attainment, or unclassifiable; severe, moderate, or marginal nonattainment)
PM-10	attainment
SO_2	attainment
NO_2	attainment
Ozone	attainment
CO	attainment
Lead	Not determined

(a) Volatile organic compounds (VOC) and oxides of nitrogen (NOx) are precursors for the formation of ozone. Therefore, VOC and NO_X emissions are considered when evaluating the rule applicability relating to the ozone standards. Jackson County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

(b) Jackson County has been classified as attainment or unclassifiable for all the other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

Source Status

Existing Source PSD or Emission Offset Definition (emissions after controls, based from the Airs Facility Subsystem Report dated January 21, 1999):

Pollutant	Emissions (tons/year)
PM	0.26
PM-10	0.26
SO_2	0.05
VOC	65.6
CO	2.99
NOx	11.97

(a) This existing source is **not** a major stationary source because no attainment regulated pollutant is emitted at a rate of 100 tons per year or more, and it is one of the 28 listed source categories.

Potential to Emit of Modification After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. The control equipment is considered federally enforceable only after issuance of this Part 70 source modification.

	Potential to Emit (tons/year)						
Process/facility	PM	PM-10	SO_2	VOC	CO	NO_X	HAPs
2 Natural gas-fired boilers	0.4	1.4	0.2	1.0	15.4	18.4	0.0
Colyte Production	0.66	0.66	0.0	0.0	0.0	0.0	0.0
Phase IIIA Production	0.28	0.28	0.0	0.0	0.0	0.0	0.0
TOTAL	1.34	2.34	0.2	1.0	15.4	18.4	0.0

This modification to an existing minor stationary source is not major because the emission increase is less than the PSD significant levels. Therefore, pursuant to 326 IAC 2-2, and 40 CFR 52.21, the PSD requirements do not apply.

Federal Rule Applicability

(b) New Source Performance Standards (NSPS):

(1) 40 CFR § 60.610, Subpart III - Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.

This NSPS applies to each air oxidation reactor unit for which Construction, Modification or Reconstruction commenced after October 21, 1983 that produces any chemical or compounds listed in this NSPS as a product, co-product, by-product or intermediate product.

The Colyte and Phase IIIA production are not subject to this NSPS because they do not involve any chemical or compound production. Colyte and Phase IIIA production mainly involves medical dry product compounding and packaging, and no VOC is emitted.

(2) 40 CFR § 60.660, Subpart NNN - Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.

This NSPS applies to each distillation unit for which Construction, Modification or Reconstruction commenced after December 30, 1983 that produces any chemical or compounds listed in this NSPS as a product, co-product, by-product or intermediate product.

The Colyte and Phase IIIA production are not subject to this NSPS because they do not involve any chemical or compound production. Colyte and Phase IIIA production mainly involves medical dry product compounding and packaging and no VOC is emitted.

(3) 40 CFR § 60.700, Subpart RRR - Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes.

This NSPS applies to each reactor process for which Construction, Modification or Reconstruction commenced after June 29, 1990 that produces any chemical or compounds listed in this NSPS as a product, co-product, by-product or intermediate product.

The Colyte and Phase IIIA production are not subject to this NSPS because they do not involve any chemical or compound production. Colyte and Phase IIIA production mainly involves medical dry product compounding and packaging and no VOC is emitted.

(4) 40 CFR § 60.40c, Subpart Dc - Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units. This rule applies to each steam generating unit for which construction, reconstruction is commenced after June 9,

1989 and that has a maximum design heat input capacity of 100 million British Thermal Units per hour (mmBtu/hr) or less, but greater than 10 mmBtu/hr.

The proposed two (2) 20.9 mmBtu/hr boilers EU–03 and EU-04 are subject to the § 60.48 Subsections (a), (g) and (i) of this NSPS.

(a) Under Subsection (a) of § 60.48, the owner/operator of the two (2) boilers shall submit notification of the date of construction, or reconstruction, anticipated startup and actual startup as provided by § 60.7 of this part. The notification shall include:

(1) The design heat input capacity of the two (2) boilers and identification of the fuel to be combusted; and

(2) the annual capacity factor at which the owner/operator anticipates operating the two (2) boilers, based on all fuels fired and based on individual fuel fired.

(b) Under Subsection (g) § 60.48, the owner/operator of the two (2) boilers shall maintain records of the amounts of fuel combusted during each month.

(c) Under Subsection (i) § 60.48, all records required in this Section shall be maintained by the owner or operator of the two (2) boilers for a period of two (2) years following the date of such record.

(b) There are no other New Source Performance Standards (NSPS)(326 IAC 12 and 40 CFR Part 60) applicable to this source.

(c) National Emission Standards for Hazardous Air Pollutants (NESHAP):
There are no National Emission Standards for Hazardous Air Pollutants (NESHAPs) applicable to the source.

State Rule Applicability - Individual Facilities

(a) 326 IAC 6-3-2 (Process Operations)
This rule mandates a PM emissions using the following equation:

Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour and
P = process weight rate in tons per hour

Facility/Operation	Process Weight Rate (ton/hr)	PM Emissions Limit (lb/hr)
Colyte Production	0.01	0.187
Phase IIIA Production	0.0044	0.11
TOTAL		0.297

These two production lines are in compliance with the rule, even without using the baghouses to control the PM emissions.

(b) 326 IAC 8-5-3 (Miscellaneous Operations: Synthesized Pharmaceutical Manufacturing Operations)

(c) This rule applies to the manufacture of pharmaceutical products by chemical synthesis. It applies to all facilities emitting volatile organic compounds, including reactors, distillation units, dryers, storage of VOC, transfer of VOC, extraction equipment, filter, crystallizers, and centrifuges, that have potential to emit 15 pounds of VOC per day.

The Colyte and Phase IIIA production are not subject to 326 IAC 8-5-3 because they don't involve any chemical synthesis. Colyte and Phase IIIA production mainly involve medical dry product compounding and packaging and no VOC is emitted.

(d) 326 IAC 8 (Volatile Organic Sources)
There are no other provisions under the Article 8 that applies to the Colyte and Phase IIIA production, because they don't emit VOC.

(e) 326 IAC 6-2-4 (PM Emission Limit for Indirect Heating Facilities)
This rule applies to indirect heating facilities constructed after September 21, 1983. The two 20.9 mmBtu/hr boilers are subject to this rule, and are mandated by this rule to have a PM emission limit as follows:

$Pt = 1.09/Q^{0.26}$
$= 0.4$ lb/mmBtu

Where: Pt = Pounds of PM emitted per million Btu (lb/mmBtu) heat input.
Q = Total source maximum operating capacity rating in mmBtu/hr
= 41.8 mmBtu/hr + existing boilers, 2 boilers @ 4.2 mmBtu/hr
= 50.2 mmBtu/hr

Using natural gas as fuel:
1.9 lb/MMCF * MMCF/1000 mmBtu = 0.002 lb/mmBtu < 0.4 lb/mmBtu (PM limit).
Therefore, the boilers are in compliance with the rule.

Conclusion

The construction of this proposed modification shall be subject to the conditions of the attached proposed Part 70 **1st Minor Source Modification No.071-11653-00023.**

Stack Summary

Stack ID	Operation	Height (feet)	Diameter (feet)	Flow Rate (acfm)	Temperature (^{0}F)
EU-01	Colyte Production Area	Rectangular		46,500	708
EU-02	Phase IIIA	Rectangular		46,500	708

Recommendation

The staff recommends to the Commissioner that the Part 70 Minor Source Modification be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on December 13, 1999. Additional information was received on January 5, 2000.

Emission Calculations

(a) Natural Gas Combustion Emissions: See Page 1 of 1 TSD Appendix A for detailed emission calculations on the two (2) proposed boilers.

(b) Colyte Production Area Emissions:

Colyte Production Process Information	
Maximum Process Weight:	3,956 pounds per batch
Full Cycle:	8 days/batch (3 days mixing & 5 days filling
Maximum no. of batches/year	66 batches/yr

Process Description	Throughput (lb/batch)	Emission factor (lb PM/ton of material)	PM=PM10 Uncontrolled Emissions (ton/year)	PM = PM10 Controlled Emissions (ton/year)
Raw Material Weigh-Up	3,956	5 lb/ton	0.33	3.3×10^{-5}
Raw Material Mixing	3,956	5 lb/ton	0.33	3.3×10^{-5}
TOTAL EMISSIONS			0.66	6.6×10^{-5}

Methodology:
PM Emissions = Throughput, lb/batch * batches/yr * ton/2000 lb * Ef, lb/ton * ton/2000 lb

(c) Phase IIIA Production Area Emissions:

Phase IIIA Production Process Information	
Maximum Process Weight:	1,690.3 pounds per batch
Full Cycle:	8 days/batch (3 days mixing & 5 days filling
Maximum no. of batches/year	66 batches/yr

Process Description	Throughput (lb/batch)	Emission factor (lb PM/ton of material)	PM=PM10 Uncontrolled Emissions (ton/year)	PM=PM10 Controlled Emissions (ton/year)
Raw Material Weigh-Up	1,690.3	5 lb/ton	0.14	1.4×10^{-5}
Raw Material Mixing & Filling of Tablets & Capsules	1,690.3	5 lb/ton	0.14	1.4×10^{-5}
TOTAL EMISSIONS			0.28	2.8×10^{-5}

Methodology:
PM Emissions = Throughput, lb/batch * batches/yr * ton/2000 lb * Ef, lb/ton * ton/2000 lb

Potential To Emit of Modification

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as "the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA."

This table reflects the PTE before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	1.34
PM-10	2.34
SO_2	0.2
VOC	1.0
CO	15.4
NO_x	18.4

Justification for Modification

The Part 70 Operating permit is being modified through a Part 70 Minor Source Modification. This modification is being performed pursuant to 326 IAC 326 IAC 2-7-10.5(d)(4), because the Oxides of Nitrogen (NOx) is emitted at a rate greater than 10 tons per year but less than 25 tons per year.

County Attainment Status

The source is located in Jackson County.

Pollutant	Status (attainment, maintenance attainment, or unclassifiable; severe, moderate, or marginal nonattainment)
PM-10	attainment
SO_2	attainment
NO_2	attainment
Ozone	attainment
CO	attainment
Lead	Not determined

(a) Volatile organic compounds (VOC) and oxides of nitrogen (NOx) are precursors for the formation of ozone. Therefore, VOC and NO_X emissions are considered when evaluating the rule applicability relating to the ozone standards. Jackson County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

(b) Jackson County has been classified as attainment or unclassifiable for all the other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

Source Status

Existing Source PSD or Emission Offset Definition (emissions after controls, based from the Airs Facility Subsystem Report dated January 21, 1999):

Pollutant	Emissions (tons/year)
PM	0.26
PM-10	0.26
SO_2	0.05
VOC	65.6
CO	2.99
NOx	11.97

(a) This existing source is **not** a major stationary source because no attainment regulated pollutant is emitted at a rate of 100 tons per year or more, and it is one of the 28 listed source categories.

Potential to Emit of Modification After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. The control equipment is considered federally enforceable only after issuance of this Part 70 source modification.

	Potential to Emit (tons/year)						
Process/facility	PM	PM-10	SO_2	VOC	CO	NO_X	HAPs
2 Natural gas-fired boilers	0.4	1.4	0.2	1.0	15.4	18.4	0.0
Colyte Production	0.66	0.66	0.0	0.0	0.0	0.0	0.0
Phase IIIA Production	0.28	0.28	0.0	0.0	0.0	0.0	0.0
TOTAL	1.34	2.34	0.2	1.0	15.4	18.4	0.0

This modification to an existing minor stationary source is not major because the emission increase is less than the PSD significant levels. Therefore, pursuant to 326 IAC 2-2, and 40 CFR 52.21, the PSD requirements do not apply.

Federal Rule Applicability

(b) New Source Performance Standards (NSPS):

(1) 40 CFR § 60.610, Subpart III - Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.

This NSPS applies to each air oxidation reactor unit for which Construction, Modification or Reconstruction commenced after October 21, 1983 that produces any chemical or compounds listed in this NSPS as a product, co-product, by-product or intermediate product.

The Colyte and Phase IIIA production are not subject to this NSPS because they do not involve any chemical or compound production. Colyte and Phase IIIA production mainly involves medical dry product compounding and packaging, and no VOC is emitted.

(2) 40 CFR § 60.660, Subpart NNN - Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.

This NSPS applies to each distillation unit for which Construction, Modification or Reconstruction commenced after December 30, 1983 that produces any chemical or compounds listed in this NSPS as a product, co-product, by-product or intermediate product.

The Colyte and Phase IIIA production are not subject to this NSPS because they do not involve any chemical or compound production. Colyte and Phase IIIA production mainly involves medical dry product compounding and packaging and no VOC is emitted.

(3) 40 CFR § 60.700, Subpart RRR - Standards of Performance for Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes.

This NSPS applies to each reactor process for which Construction, Modification or Reconstruction commenced after June 29, 1990 that produces any chemical or compounds listed in this NSPS as a product, co-product, by-product or intermediate product.

The Colyte and Phase IIIA production are not subject to this NSPS because they do not involve any chemical or compound production. Colyte and Phase IIIA production mainly involves medical dry product compounding and packaging and no VOC is emitted.

(4) 40 CFR § 60.40c, Subpart Dc - Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units. This rule applies to each steam generating unit for which construction, reconstruction is commenced after June 9,

1989 and that has a maximum design heat input capacity of 100 million British Thermal Units per hour (mmBtu/hr) or less, but greater than 10 mmBtu/hr.

The proposed two (2) 20.9 mmBtu/hr boilers EU–03 and EU-04 are subject to the § 60.48 Subsections (a), (g) and (i) of this NSPS.

(a) Under Subsection (a) of § 60.48, the owner/operator of the two (2) boilers shall submit notification of the date of construction, or reconstruction, anticipated startup and actual startup as provided by § 60.7 of this part. The notification shall include:

(1) The design heat input capacity of the two (2) boilers and identification of the fuel to be combusted; and

(2) the annual capacity factor at which the owner/operator anticipates operating the two (2) boilers, based on all fuels fired and based on individual fuel fired.

(b) Under Subsection (g) § 60.48, the owner/operator of the two (2) boilers shall maintain records of the amounts of fuel combusted during each month.

(c) Under Subsection (i) § 60.48, all records required in this Section shall be maintained by the owner or operator of the two (2) boilers for a period of two (2) years following the date of such record.

(b) There are no other New Source Performance Standards (NSPS)(326 IAC 12 and 40 CFR Part 60) applicable to this source.

(c) National Emission Standards for Hazardous Air Pollutants (NESHAP):
There are no National Emission Standards for Hazardous Air Pollutants (NESHAPs) applicable to the source.

State Rule Applicability - Individual Facilities

(a) 326 IAC 6-3-2 (Process Operations)
This rule mandates a PM emissions using the following equation:

Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour and
P = process weight rate in tons per hour

Facility/Operation	Process Weight Rate (ton/hr)	PM Emissions Limit (lb/hr)
Colyte Production	0.01	0.187
Phase IIIA Production	0.0044	0.11
TOTAL		0.297

These two production lines are in compliance with the rule, even without using the baghouses to control the PM emissions.

(b) 326 IAC 8-5-3 (Miscellaneous Operations: Synthesized Pharmaceutical Manufacturing Operations)

(c) This rule applies to the manufacture of pharmaceutical products by chemical synthesis. It applies to all facilities emitting volatile organic compounds, including reactors, distillation units, dryers, storage of VOC, transfer of VOC, extraction equipment, filter, crystallizers, and centrifuges, that have potential to emit 15 pounds of VOC per day.

The Colyte and Phase IIIA production are not subject to 326 IAC 8-5-3 because they don't involve any chemical synthesis. Colyte and Phase IIIA production mainly involve medical dry product compounding and packaging and no VOC is emitted.

(d) 326 IAC 8 (Volatile Organic Sources)
There are no other provisions under the Article 8 that applies to the Colyte and Phase IIIA production, because they don't emit VOC.

(e) 326 IAC 6-2-4 (PM Emission Limit for Indirect Heating Facilities)
This rule applies to indirect heating facilities constructed after September 21, 1983. The two 20.9 mmBtu/hr boilers are subject to this rule, and are mandated by this rule to have a PM emission limit as follows:

$Pt = 1.09/Q^{0.26}$
$= 0.4$ lb/mmBtu

Where: Pt = Pounds of PM emitted per million Btu (lb/mmBtu) heat input.
Q = Total source maximum operating capacity rating in mmBtu/hr
= 41.8 mmBtu/hr + existing boilers, 2 boilers @ 4.2 mmBtu/hr
= 50.2 mmBtu/hr

Using natural gas as fuel:
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Therefore, the boilers are in compliance with the rule.

Conclusion

The construction of this proposed modification shall be subject to the conditions of the attached proposed Part 70 **1st Minor Source Modification No.071-11653-00023.**

Appendix A: Emissions Calculations
Natural Gas Combustion Only
MM BTU/HR <100
Small Industrial Boiler

Company Nai **Schwarz Pharma USA, Inc.**
Address City **1101 "C" Avenue West, Freeman Field, Seymour, IN**
CP: **071-11653**
Plt ID: **071-00023**
Reviewer: **Aida De Guzman**
Date: **Dec. 21, 1999**

2 boilers @ 20.9 mmBtu/hr

Heat Input Capacity MMBtu/hr	Potential Throughput MMCF/yr
20.9	183.1
20.9	183.1

	Pollutant					
	PM*	PM10*	SO2	NOx	VOC	CO
Emission Factor in lb/MMCF	1.9	7.6	0.6	100.0 **see below	5.5	84.0
Potential Emission in tons/yr	0.2	0.7	0.1	9.2	0.5	7.7
Potential Emission in tons/yr	0.2	0.7	0.1	9.2	0.5	7.7
Total Potential Emissions in tons/yr	0.4	1.4	0.2	18.4	1.0	15.4

*PM emission factor is filterable PM only. PM10 emission factor is filterable and condensable PM10 combined.

**Emission Factors for NOx: Uncontrolled = 100, Low NOx Burner = 50, Low NOx Burners/Flue gas recirculation = 32

Methodology

All emission factors are based on normal firing.

MMBtu = 1,000,000 Btu

MMCF = 1,000,000 Cubic Feet of Gas

Potential Throughput (MMCF) = Heat Input Capacity (MMBtu/hr) x 8,760 hrs/yr x 1 MMCF/1,000 MMBtu

Emission Factors are from AP 42, Chapter 1.4, Tables 1.4-1, 1.4-2, 1.4-3, SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03 (SUPPLEMENT D 3/98)

Emission (tons/yr) = Throughput (MMCF/yr) x Emission Factor (lb/MMCF)/2,000 lb/ton

above
emission